## Safety Concerns for the HPV vaccine: Gardasil

- Gardasil was licensed in 2006 and up to September 2012 there were 21,265 adverse events (AE's) reported to the US CDC and FDA alone 14. Globally there have been many more AE's associated with HPV vaccines. The US CDC data includes 78 deaths, 363 life-threatening events, 609 permanently disabled, 2,000 cases listed as serious or prolonged hospitalisation and 9,565 requiring an emergency room visit 14.
- This is only a proportion of the AE's because the US CDC monitoring system and Australia's TGA monitoring system are *passive* surveillance systems 24. This means they rely on voluntary reporting of temporal events *only*. As vaccine ingredients can cause delayed adverse events the only type of system that would be able to establish causal relationships with adverse events is an *active* surveillance system: one that follows the health outcomes for every vaccinated individual for a minimum of 1 year.
- The CDC and the TGA admit that the surveillance systems cannot establish causal relationships between the vaccine and the adverse events. This allows the government to claim that the adverse events are a 'coincidence'. This is not a scientific evidence-based policy.
- It is known that passive reporting systems will only represent about one-tenth of the possible adverse events that actually occur 20. Any delayed reactions will not be reported.
- Despite the voluntary reporting of adverse events Gardasil has been responsible for 61% of all serious AE's compared to all other vaccines in the US vaccination schedule (including 63.8% of all deaths and 81.2% of all cases of permanent disability) in females younger than 30 years of age 14.
- HPV vaccine contains genetically modified DNA 13

- Gardasil contains 225 micrograms of aluminium adjuvant (225 ug amorphous aluminium hydroxyphosphate sulphate). Many times more than most vaccines and this adjuvant is known to cause allergies/anaphylaxis and autoimmune reactions in humans 20
- The trials did not use a true placebo to test the safety of the vaccine. The manufacturer funded clinical trials used the adjuvant, aluminium hydroxyphosphate sulphate (classified as a neuro-immunotoxic substance) as the placebo in the unvaccinated group and this substance does not allow the researchers to accurately compare the adverse health outcomes that might occur from the vaccine with a group that is completely unvaccinated..
- For example, in the pre-licensure clinical trial for Gardasil there were 245 serious reactions (indicative of an autoimmune disease) from the 'vaccine' group and 218 from the 'aluminium hydroxyphosphate sulphate' group. How would these figures compare to a group with no vaccine or aluminium adjuvant? This is a flaw in the experimental design of the trial 22.
- Other ingredients of the vaccine include: sodium borate (borax), polysorbate 80, L-histidine hydrochloride, 4 recombinant VLP's: HPV types 16, 18, 11 and 6, amino Acids, carbohydrates, mineral salts, vitamins 13
- There are an unusually high number of AE's associated with HPV vaccines with nervoussystem-related disorders ranking the highest in frequency 14. When the global reports of adverse events are pooled for Gardasil the data suggests that the risks of HPV vaccination have not been fully evaluated in the pre-licensure trials 14.
- Yet the US CDC and the Australian TGA are evaluating selective data (not the global safety data) and they are concluding that 'HPV vaccines are safe and effective'.

- The many known side-effects from HPV vaccines include death and life-long neurodegenerative/autoimmune disorders. These are documented in the pre-licensure clinical trials and at <a href="https://www.sanevax.org">www.sanevax.org</a>
- Over the past 2 decades pharmaceutical companies have gained unprecedented control
  over the evaluation and registration of their own products 14. This fact is reflected in the
  poorly designed safety and efficacy trials for vaccines for which there is no
  accountability.
- This is particularly the case because many vaccines are licensed in the USA where vaccine manufacturers are legally free from ordinary tort liability 23. Vaccines are a product that are described as 'unavoidably unsafe' and there is no onus on manufacturers to make them as safe as possible because they are free from liability 23
- Parents must ask if they wish their children to be subjected to the risk from a vaccine that
  has not been proven to prevent cervical cancer when there is already a safe and effective
   PAP screening procedure that will still be required anyway 14.

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## **References:**

- International Agency for Research on Cancer (WHO), 1995, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, volume 64, Human Papillomaviruses
- 2. Pfister H (Ed.), 1990, Papillomaviruses and Human Cancer, CRC Press Inc, USA

- 3. Australian Government, Department of Health and Ageing, 2005, "Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen detected abnormalities, NHMRC, National Screening Program.
- Haverkos H, 2005, Multifactorial Etiology of Cervical Cancer: A Hypothesis,
   Medscape General Medicine, v 7 (4): 57
- Australian Government, Department of Health and Ageing, Office of Health Protection, 2009.
- Future II Study Group, 2007, Quadrivalent Vaccine against Human Papillomavirus to Prevent High-Grade Cervical Lesions, *The New England Journal of Medicine*, 356, 19, 1915 – 27.
- 7. Dayton L, 2011, The Australian, Ian Frazer's HPV vaccine may prevent cervical cancer, 19<sup>th</sup> June
- 8. Walboomers J, Jacobs M, Manos M, Bosch X, Kummer J, Shah K, Snijders P, Peto J, Meijer C, Munoz N, 1999, Human papillomavirus is a necessary cause of Invasive Cervical Cancer Worldwide, *Journal of Pathology*, vol. 189 p.12-19
- 9. Parkin DM, Bray F, Ferlay J, Pisani P, 2005, Global Cancer Statistics 2002, *CA: A Cancer Journal for Clinicians*, 2005; 55; 74-108
- Australian of the Year Awards 2012, Australian of the Year 2006,
   <a href="http://www.australianoftheyear.org.au/pages/page58.asp">http://www.australianoftheyear.org.au/pages/page58.asp</a> visited November 2011
- 11. Clifford et al, 2005, Worldwide distribution of human papillomavirus types in cytologically normal women in the International Agency for Research on Cancer HPV prevalence surveys: a pooled analysis, *The Lancet*, Vol 366, Is. 9490,2005,Pages 991-998

- Australian Government, NCIRS, Human papillomavirus (HPV) Fact Sheet,
   <a href="http://www.ncirs.edu.au/immunisation/fact-sheets/hpv-human-papillomavirus-fact-sheet.pdf">http://www.ncirs.edu.au/immunisation/fact-sheets/hpv-human-papillomavirus-fact-sheet.pdf</a>
   updated March 2013
- Merck Inc, Clinical Review of Biologics License Application for Human
   Papillomavirus 6, 11, 16, 18, L1 Virus Like Particle Vaccine (S. cerevisiae) STN
   125126 GARDASIL), 2006 (June 8), manufactured by Merck Inc.
- 14. Tomljenovic L, Shaw CA, 2012, Too fast or not too fast: the FDA's approval of Merck's HPV vaccine gardasil, *Journal of Law, medicine and Ethics*, 40 (3):673-681
- Moscicki et al 2010 in Tomljenovic L, Wilyman J, Vanamee E, Bark T, Shaw C,
   2013, HPV vaccines and cancer prevention, science versus activism, *Infectious Agents and Cancer Journal*, 8:6
- 16. Herskovits B. 2007, Brand of the Year, *Pharmaceutical Executive*, 27 (2): 58-65
- 17. a) Brisson M, Van de Velde N, Boily MC, Economic evaluation of human papillomavirus vaccination in developed countries, *Public Health Genomics*, August(5-6) 2009, vol 12: p 343 -51
  - b) Choi YH, Chaoman R, Gay N, Jit M, Potential overestimation of HPV vaccine impact due to unmasking of non-vaccine types: Quantification using a multi-type mathematical model, *Vaccine*, 2012, vol 30: p 3383 8
- 18. CSL Limited, Research and Development, Recent Highlights, Gardasil
  <a href="http://www.csl.com.au/research-development/recent-highlights.htm">http://www.csl.com.au/research-development/recent-highlights.htm</a> visited November
  2011
- Uniquest, Technology Investment and Licensing, Gardasil Human papilloma Virus
   Vaccine, <a href="https://www.uniquest.com.au/portfolio/gardasil-human-papilloma-virus-vaccine">https://www.uniquest.com.au/portfolio/gardasil-human-papilloma-virus-vaccine</a> visited November 2011

- S.A.N.E Vax Inc. Safe, Affordable, Necessary and Effective Vaccines,
   www.sanevax.org visited 28 April 2011
- 21. Shoenfeld Y and Agmon-Levin N, 2011, ASIA Autoimmunity/inflammatory syndrome induced by adjuvants, *Journal of Autoimmunity*, 36 p. 4-8.
- 22. C Exley, 2011, Aluminium-based adjuvants should not be used as placebos in clinical trials, *Vaccine*, 29, no. 50: 9289
- 23. 1986 National Childhood Vaccine Injury Act in Habakus and Holland 2011, Vaccine Epidemic: how corporate greed, biased science and coercive government threaten our human rights, our health and our children, Center for Personal Rights Inc, Skyhorse Publishing, 306<sup>th</sup> St New York ch 1.
- 24. US Centers for Disease Control and Prevention (CDC), Vaccine Safety, Reports of Health concerns following HPV Vaccination, <a href="https://www.cdc.gov/vaccinesafety/vaccines/hpv/gardasil.html">www.cdc.gov/vaccinesafety/vaccines/hpv/gardasil.html</a> visited Dec 2011.